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U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICESUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENTDocket Number:  
1662/61902Application Number  
10/699,991Filing Date  
November 3, 2003Examiner  
Not Yet AssignedArt Unit  
1614Invention Title  
PHARMACEUTICAL COMPOSITIONS AND  
DOSAGE FORMS FOR BUCCAL AND  
SUBLINGUAL DELIVERY OF TIZANIDINE  
AND METHODS OF ADMINISTERING  
TIZANIDINE SUBLINGUALLY OR BUCCALLYInventors  
E. Itzhak LERNER et al.Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450I hereby certify that this correspondence is being deposited with  
the United States Postal Service with sufficient postage as first  
class mail in an envelope addressed to:  
Commissioner for Patents, P.O. Box 1450, Alexandria, VA  
22313-1450 on

Date:

8/14/06

Signature:

Jessica Felty  
Jessica Felty

Sir:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). The paragraphs marked below are applicable. It is believed that no fees other than those indicated below are due, but authorization is hereby given to charge any additional fees due, or to credit any overpayment, to **Kenyon & Kenyon LLP, deposit account 11-0600**.

☒ 1. This Information Disclosure Statement is being filed (a) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53(d), (b) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, (c) before the mailing date of a first Office Action on the merits in the present application, OR (d) before the mailing of a first office action after filing of a request for continued examination. No certification or fee is required.

☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a final action, Notice of Allowance, or any action that otherwise closes prosecution.

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- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).
- ☐ c. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 CFR §1.97(c)(2).
- ☐ 3. This Information Disclosure Statement is being filed after the mailing date of a final action, Notice of Allowance or an action that otherwise closes prosecution, but before payment of the Issue Fee. Applicant(s) hereby request(s) that the Information Disclosure Statement be considered. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the petition fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in any counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).
- ☐ 4. Relevance of the non-English language reference(s) is discussed in the present specification.
- ☐ 5. The references were cited in office actions in counterpart foreign applications. English language version of the foreign corresponding foreign office actions and responses thereto are attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language reference(s) appears in the Appendix attached hereto.
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is

respectfully requested to consider the cited application and the art cited therein during examination of the present application.

☐ 8. This application is one of a series of related applications, identified in the attached Appendix, which are directed to related technical subject matter. The identification of those U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during the examination.

☐ 9. The reference(s) was/were cited by or submitted to the Office in parent application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).

☐ 10. English-language Abstracts of the non-English language references are attached hereto.

☒ 11. Since this application was filed after June 30, 2003, copies of U.S. references are not included.

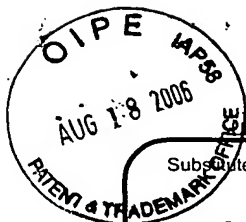
☐ 12. Other. The references cited herein were cited in an International Search Report of \_\_\_\_\_ provided herewith.

Respectfully submitted,

Date:

8/14/06

  
Craig L. Puckett (Reg. No. 43,023)  
KENYON & KENYON LLP  
One Broadway  
New York, New York 10004  
(212) 425-7200 (telephone)  
(212) 425-5288 (facsimile)  
**CUSTOMER NUMBER 26646**



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

**Complete if Known**

Application Number	10/699,991
Filing Date	November 3, 2003
First Named Inventor	E. Itzhak LERNER et al.
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	1662/61902

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		6,255,502	Jul 3, 2001	Lawrence John Penkler et al.	
		6,248,363	Jun 19, 2001	Mahesh V. Patel et al.	
		5,466,464	Nov 14, 1995	Katsuhiro Masaki et al.	
		2003/0206954	Nov 6, 2003	E. Itzhak Lerner et al.	
		5,702,717	Dec 30, 1997	Younsik Cha et al.	
		6,201,072	Mar 13, 2001	Ramesh C. Rathi et al.	
		6,117,949	Sept 12, 2000	Ramesh C. Rathi et al.	
		6,004,573	Dec 21, 1999	Ramesh C. Rathi et al.	
		3,632,743	Jan 4, 1972	Leo Geller et al.	
		2,698,822	Jan 4, 1955	Alfred Halpern et al.	
		3,444,858	May 20, 1969	Higham S. Russell	
		3,870,790	Mar 11, 1975	Hans Lowey et al.	
		3,972,995	Aug 3, 1976	Andrew G. Tsuk et al.	
		4,229,447	Oct 21, 1980	William R. Porter	
		4,020,558	May 3, 1977	René Cournut et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 03/057136 A2	Jul 17, 2003	Teva Pharmaceutical Industries Ltd.		
		WO 03/057136 A3	Jul 17, 2003	Teva Pharmaceutical Industries Ltd.		
		WO 99/04764	Feb 4, 1999	Perio Products Ltd.		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Remington's Pharmaceutical Sciences 16 <sup>th</sup> ed., page 670, (Mack Publishing: Easton, Pa. 1980).	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.